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(54) **BRANCH VESSEL STENT GRAFT**

ZWEIGGEFÄSS-STENT

ENDOPROTHESE VASCULAIRE BIFURQUEE

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Description

[0001] This invention relates to a medical device and more particularly to a medical device for endovascular deployment into a body lumen such as the vasculature of an animal or human.

[0002] It is known to use branch vessel stent grafts deployed into vasculature of a human or animal to provide an alternate flow path where the vasculature has been damaged by accident or disease. The branch vessel stent graft allows an extension piece to be deployed from a main graft into a side vessel of the vasculature so that blood flow can enter the side vessel.

[0003] The conventional procedure to treat branch vessels utilizes a balloon expandable covered stent-which is deployed through the side arm ofthe stent graft to connect the side vessels to a bifurcated stent graft. The limitation of a delivery system for such balloon expandable covered stents is normally 7 to 8 French which makes the design of the stent graft deployment system challenging. A further challenge is then providing a sufficient attachment between the branch vessel stent graft and the side arm ofthe main graft since endoleaks can occur and these are of significant concern. A stent graft according to the preamble of claim 1 is known from the document US-A-2004/0082990.

[0004] It is the object of this invention to provide an alternative branch vessel stent graft which will make the process of deployment of a graft into a branch vessel more straightforward or at least to provide the physician with a useful alternative.

[0005] Throughout this specification the term distal with respect to a portion of the aorta, a deployment device or a prosthesis is the end of the aorta, deployment device or prosthesis further away in the direction of blood flow away from the heart and the term proximal means the portion of the aorta, deployment device or end of the prosthesis nearer to the heart. When applied to other vessels similar terms such as caudal and cranial should be understood.

[0006] According to an aspect of the present invention, there is provided a stent graft as specified in claim 1.

[0007] Preferably the tubular body and the side arm comprise a biocompatible woven or non-woven material selected from the group comprising Dacron and expanded PTFE and the extension piece comprises an elastomeric biocompatible material such as Thoralon™.

[0008] Preferably the extension piece is unstented. The extension piece may comprise, however, a longitudinally extending resilient reinforcement. The longitudinally extending resilient reinforcement may be a ribbon or wire formed from nitinol. The longitudinally extending resilient reinforcement is preferably embedded in the extension piece.

[0009] There can also be placed gold markers embedded in the extension piece to assist with visualisation using radiographic techniques during deployment.

[0010] The unstented extension piece is supported after deployment by a separately deployed self expanding stent assembly or by a separately deployed balloon expandable stent assembly. The separately deployed self expanding stent assembly or a separately deployed balloon expandable stent assembly may have at least one radiopaque marker to assist with visualisation using radiographic techniques during deployment.

[0011] Preferably the tubular body comprises a plurality of self expanding stents and the side arm is stitched to the tubular body. The extension piece is preferably sealingly joined to the side arm by being adhered thereto.

[0012] Alternatively the extension piece is stitched to the side arm using a biocompatible suture material.

[0013] Where the extension piece comprises Thoralon™ it may be sealingly fastened to the side arm by being adhered thereto by the use of a Thoralon™ solution as an adhesive.

[0014] The tubular body is bifurcated and the extension piece comprises a leg extending from a bifurcation in the tubular body.

[0015] According to a second aspect of the present invention, there is provided a kit as specified in claim 14.

[0016] It will be seen that by this invention the stent for the extension piece is deployed in a separate stage than the deployment of the actual graft for the side arm and therefore makes it easier to use any bare stent such as a self expanding or balloon expandable stent for the stent stage. Such a separately deployed bare stent is considerably smaller in diameterthan a covered balloon expandable stent for instance and therefore can be more easily deployed using existing technologies. The graft portion of the side branch is attached securely to the main side arm stent graft and loaded as an integral part. After the stent graft is implanted a bare stent can then subsequently be deployed to keep the branch vessel graft open and attached to the vasculature.

[0017] This arrangement has two significant advantages. First of all there can be a lower system delivery profile for the stent for the side arm.

[0018] A second advantage is that effective sealing can be obtained because the extension piece for the side arm is effectively sealed to the extension piece during manufacture of the stent graft.

[0019] This then generally describes the invention but to assist with understanding reference will now be made to the accompanying drawings which show preferred embodiments of the invention.

In the drawings:

Figure 1 shows a first view of a side branch stent graft with an extension piece according to one embodiment of the present invention;

Figure 2 shows the embodiment shown in Figure 1 with the extension piece folded back into the side arm for initial deployment;

Figure 3 shows the side arm stent graft and extension piece of Figure 1 after deployment and placement of a bare self expanding stent deployed through the

extension piece;

Figure 4 shows a detail of the side arm of Figure 2 particularly showing the folded back nature of the extension piece and the radio opaque marker;

Figure 5 shows detail of an alternative embodiment of stent graft according to the invention in which the extension piece includes a reinforcing ribbon;

Figure 6 shows an alternative embodiment ofstent graft according to the invention including an extension piece according to the present invention;

Figure 7 shows the embodiment of Figure 6 with the extension piece retracted for deployment; and

Figure 8 shows an alternative method of joining the extension piece to the side arm according to the present invention.

[0020] Now looking more closely at the first embodiment of the invention shown in Figures 1, 2, and 4 it will be seen that the stent graft 10 according to the present invention comprises a tubular body 12 of a biocompatible graft material such as Dacron supported by a plurality of self expanding zigzag Gianturco stents 14. At least the self expanding stent 16 at the distal end 18 of the stent graft 10 is internal and the other stents are preferably external. A side arm 20 is stitched into the main body by stitching 22 and extends away from the body at an angle towards the distal end of the stent graft. The side arm is formed from a biocompatible graft material such as Dacron. U.S. Provisional Patent Application Serial No. 60/611,744, filed September 21,2004, U.S. Patent Application Serial No. 11/231,621, filed September 21,2005, and Published on May 4, 2006, as U.S. Patent Application Publication No. US-2006/0095118-A1, and PCT Patent Publication No. WO 06/034276 entitled "Side Branch Stent Graft" disclose methods of joining the side arm to the tubular body of the stent graft. This feature and other features disclosed in U.S. Provisional Patent Application Serial No. 60/611,744, filed September 21, 2004, U.S. Patent Application Serial No. 11/231,621, filed September 21,2005, and Published on May 4, 2006, as U.S. Patent Application Publication No. US-2006/0095118-A1, and PCT Patent Publication No. WO 06/034276 could be used with the present invention and the disclosure of U.S. Provisional Patent Application Serial No. 60/611,744, filed September 21,2004, U.S. Patent Application Serial No. 11/231,621, filed September 21,2005, and Published on May 4,2006, as U.S. Patent Application Publication No. US-2006/0095118-A1, and PCT Patent Publication No. WO 06/034276. Other forms of connection ofthe side arm to the tubular body as well as side arms that are integral with the tubular body are within the scope of the invention.

[0021] An extension piece 24 extends from the side arm 20 with an overlapped portion 26. The extension piece 24 is formed from Thoralon™ which is a polyurethane multi-polymer comprising a high flex life elastomer base with a surface modifying agent comprising siloxane which is manufactured by Thorotec Corporation (Pleasanton, CA USA). This material is substantially transparent and hence the distal end 27 of the side arm 20 can be seen through it.

[0022] The extension piece 24 can be adhered to the side arm 20 in the overlap region by use of a Thoralon™ solution. One method by which a Thoralon tube may be adhered to the biocompatible graft material side arm 20 is as follows. The overlapping portion 26 of the side arm is first soaked with low concentration Thoralon solution and then it is dried. The tubular Thoralon graft is then adhered onto the overlapping portion 26 by using a Thoralon solution and the solution is cured.

[0023] A first advantage of using Thoralon™ is that even after it is compressed into a small size for deployment it is resilient and can return to its original shape after deployment. This makes it possible to deploy the extension piece into a vessel.

[0024] A further advantage is that the Thoralon™ polymer is particularly hemocompatible because of the siloxane continually migrates to the blood-contacting surfaces to inhibit the attachment of proteins such as fibrin thereto.

[0025] Figure 2 and Figure 4 show the arrangement of the extension piece during deployment. It will be seen that the extension piece 24 is folded back inside itself and inside the side arm 20 but with its distal end 30 adjacent the distal end 27 of the side arm 20. In Figure 4 in particular it can be seen also that there is a radiopaque marker 28 embedded into the Thoralon™ extension piece 24 to assist with visualisation during deployment.

[0026] Figure 3 shows the side arm stent graft and extension piece of Figure 1 after deployment and placement of a bare self expanding stent deployed through the extension piece. A bare stent 32 has been deployed partly within the side arm 20 and partly within the extension piece 24 and just extending out of the distal end 30 of the extension piece 24. The bare stent 32 has a radiopaque marker 34 mounted into its distal end 35 to assist with visualisation and accurate placement during deployment. The bare stent 32 can be a self expanding stent such as a Zilver™ stent (Cook, Bloomington, IN USA) or a balloon expandable stent carried in and deployed on a balloon catheter. A deployment device or introducer for such a bare stent may have a diameter of 7 French which is compatible with existing delivery systems for stent grafts. It will be noted from Figure 3 that the radiopaque marker 28 embedded into the Thoralon™ extension piece 24 is now some distance from the side arm 20 so that the physician is able to determine by radiography whether successful extension of the extension piece has occurred.

[0027] Figure 5 shows detail of an alternative embodiment of side arm stent graft with extension piece. In this embodiment the side arm 40 of a stent graft has an extension piece 42 fastened to it on the outside of the side arm 40 by the use of a Thoralon™ adhesive 46. One method of fastening is by adhering as discussed above. The extension piece 42 has a ribbon 44 of nitinol embed-

ded into it and extending longitudinally along the extension piece. By this arrangement when the extension piece is extended from the position where it is retracted within the side arm as shown in Figure 4 for instance to the extended configuration as shown in Figure 1 for instance the nitinol ribbon assists with straightening and reinforcing the extension piece. Hence the nitinol ribbon 44 provides a resilient reinforcement for the extension piece 42. Alternatively the reinforcement may be a resilient wire. The wire or ribbon may alternatively be formed from resilient stainless steel.

[0028] Figure 6 shows an alternative embodiment of stent graft according to the invention including an extension piece according to the present invention, and Figure 7 shows the embodiment of Figure 6 with the stent graft part cutaway to show the extension piece retracted into the stent graft for deployment.

[0029] In Figure 6 there is illustrated a bifurcated stent graft suitable for deployment into an aorta to span an aneurysm which incorporates the aortic bifurcation. The stent graft 50 has a tubular body 52 and a first leg 54 extending from a bifurcation 55. A second leg extending from the bifurcation 55 is comprised partly as a leg 57 being a continuation of the tubular body 52 and then an extension piece 59 comprised from a elastomeric material such as expanded PTFE or Thoralon. The extension piece 59 is fastened to the leg 57 by adhering as discussed above or any other fastening technique such as stitching.

[0030] Figure 7 shows the embodiment of Figure 6 but part of the tubular body 52 is cutaway to show the extension piece 59 folded back into the main tubular body for deployment.

[0031] Upon deployment of the stent graft according to this embodiment the stent graft is deployed so that the tubular body 52 is in the aorta and the leg 54 extends down one of the iliac arteries and then the extension piece 59 can then be pushed outto extend down the contra-lateral iliac artery and then a bare stent such as a self expanding or balloon expandable stent can be deployed into the contra-lateral iliac artery to seal the extension piece against the wall of the contra-lateral iliac artery.
The extension piece may include a reinforcing ribbon or wire of nitinol or stainless steel and may include one or more radiopaque markers.

[0032] Figure 8 shows an alternative method of joining the extension piece to the side arm according to the present invention. In this embodiment the side arm 60 of a stent graft has an extension piece 62 of a biocompatible elastomeric material stitched to it by stitching 64. The stitching provides a fluid type seal between the extension piece and the side arm which reduce the chance of endoleaks after deployment of the stent graft into the vasculature of a patient.

Claims

1. A stent graft (10; 50) comprising a tubular body (12; 52) of a biocompatible material with a main lumen therethrough, a side arm (20; 40; 57; 60) extending from the tubular body with a side arm lumen therethrough and being fastened to the tubular body, the side arm having a distal end (27) remote from its connection to the tubular body, the main lumen being in fluid communication with the side arm lumen **characterised by** an unstented tubular extension piece (24; 42; 59; 62) sealingly fastened to the distal end of the side arm and extending therefrom, wherein the tubular extension piece is tucked back into the side arm for deployment of the stent graft into a body lumen and is extendable from the side arm during deployment of the stent graft.

2. A stent graft (10; 50) as claimed in claim 1, wherein the tubular extension piece (24; 42; 59; 62) is tucked back inside the side arm (20; 40; 57; 60) such that its distal end (30) is adjacent the distal end (27) of the side arm.

3. A stent graft (50) as claimed in claim 1 or 2, wherein the tubular body is a bifurcated tubular body (52) and wherein the side arm is a leg (57) of the bifurcated tubular body.

4. A stent graft (10; 50) as claimed in claim 1, 2 or 3, wherein the tubular body (12; 52) and the side arm (20; 40; 57; 60) comprise a biocompatible woven or non-woven material of Dacron or expanded PTFE.

5. A stent graft (10; 50) as claimed in any preceding claim, wherein the extension piece (24; 42; 59; 62) comprises an elastomeric biocompatible material of Thoralon™ polymer or expanded PTFE.

6. A stent graft (10; 50) as claimed in any preceding claim, wherein the extension piece (42) includes a longitudinally extending resilient reinforcement (44).

7. A stent graft (10; 50) as claimed in claim 6, wherein the longitudinally extending resilient reinforcement comprises a ribbon (44) or wire formed from nitinol.

8. A stent graft (10; 50) as claimed in claim 6 or 7, wherein the longitudinally extending resilient reinforcement (44) is embedded in the extension piece (42).

9. A stent graft (10; 50) as claimed in any preceding claim, wherein the extension piece (24; 42; 59) is sealingly fastened to the side arm (20; 40; 57) by being adhered thereto.

10. A stent graft (10; 50) as claimed in any preceding

claim, wherein the extension piece (24; 42; 59) comprises Thoralon™ polymer and the extension piece is fastened to the side arm (20; 40; 57) by being adhered thereto by the use of a Thoralon™ solution.

11. A stent graft (10; 50) as claimed in any of claims 1 to 8, wherein the extension piece (62) is fastened to the side arm (60) by being stitched thereto.

12. A stent graft (10; 50) as claimed in any preceding claim, comprising a radiopaque marker (28) embedded into the extension piece (24; 42; 59; 62).

13. A stent graft (10; 50) as claimed in any preceding claim, wherein the extension piece (42) includes a longitudinally extending resilient reinforcement (44) embedded therein, the extension piece comprises Thoralon™ polymer or expanded PTFE, and wherein at least one radiopaque marker (28) is embedded into the extension piece.

14. A kit including a stent graft (10; 50) as claimed in any preceding claim, and a separately deployable self-expanding stent assembly or a separately deployable balloon expandable stent assembly.

Patentansprüche

1. Stentimplantat (10; 50) mit einem röhrenförmigen Körper (12; 52) aus einem biokompatiblen Material mit einem durch ihn hindurch gehenden Hauptlumen, einem Seitenarm (20; 40; 57; 60), der sich von dem röhrenförmigen Körper mit einem Seitenarmlumen durch ihn hindurch erstreckt und an dem röhrenförmigen Körper befestigt ist, wobei der Seitenarm ein distales Ende (27) entfernt von seiner Verbindung mit dem röhrenförmigen Körper aufweist, wobei das Hauptlumen mit dem Seitenarmlumen in Fluidverbindung steht, **gekennzeichnet durch** ein röhrenförmiges Verlängerungsstück (24; 42; 59; 62) ohne Stent, das dichtend an dem distalen Ende des Seitenarms befestigt ist und sich von diesem erstreckt, worin das röhrenförmige Verlängerungsstück zum Einsetzen des Stentimplantats in ein Körperlumen zurück in den Seitenarm gesteckt wird und beim Einsetzen des Stentimplantats aus dem Seitenarm ausgezogen werden kann.

2. Stentimplantat (10; 50) nach Anspruch 1, worin das röhrenförmige Verlängerungsstück (24; 42; 59; 62) zurück in den Seitenarm (20; 40; 57; 60) gesteckt wird, so dass sein distales Ende (30) neben dem distalen Ende (27) des Seitenarms liegt.

3. Stentimplantat (50) nach Anspruch 1 oder 2, worin der röhrenförmige Körper ein gegabelter röhrenförmiger Körper (52) ist und worin der Seitenarm ein Schenkel (57) des gegabelten röhrenförmigen Körpers ist.

4. Stentimplantat (10; 50) nach Anspruch 1, 2 oder 3, worin der röhrenförmigen Körper (12; 52) und der Seitenarm (20; 40; 57; 60) ein biokompatibles gewebtes oder Vliesmaterial aus Dacron oder expandiertem PTFE umfassen.

5. Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, worin das Verlängerungsstück (24; 42; 59; 62) ein elastomeres biokompatibles Material aus Thoralon™ Polymer oder expandiertem PTFE umfasst.

6. Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, worin das Verlängerungsstück (42) eine sich in Längsrichtung erstreckende nachgiebige Verstärkung (44) aufweist.

7. Stentimplantat (10; 50) nach Anspruch 6, worin die sich in Längsrichtung erstreckende nachgiebige Verstärkung ein Band (44) oder einen Draht aus Nitinol umfasst.

8. Stentimplantat (10; 50) nach Anspruch 6 oder 7, worin die sich in Längsrichtung erstreckende Verstärkung (44) in dem Verlängerungsstück (42) eingebettet ist.

9. Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, worin das Verlängerungsstück (24; 42; 59) dichtend an dem Seitenarm (20; 40; 57) befestigt ist, indem es daran festgeklebt ist.

10. Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, worin das Verlängerungsstück (24; 42; 59) Thoralon™ Polymer umfasst und das Verlängerungsstück an dem Seitenarm (20; 40; 57) befestigt ist, indem es durch Verwendung einer Thoralon™ Lösung daran festgeklebt ist.

11. Stentimplantat (10; 50) nach einem der Ansprüche 1 bis 8, worin das Verlängerungsstück (62) an dem Seitenarm (60) befestigt ist, indem es daran angenäht ist.

12. Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, eine röntgenopake Markierung (28) umfassend, die in dem Verlängerungsstück (24; 42; 59; 62) eingebettet ist.

13. Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, worin das Verlängerungsstück (42) eine darin eingebettete, sich in Längsrichtung erstreckende nachgiebige Verstärkung (44) aufweist, wobei das Verlängerungsstück Thoralon™ Polymer oder expandiertes PTFE umfasst und worin

zumindest eine röntgenopake Markierung (28) in dem Verlängerungsstück eingebettet ist.

14. Ausrüstung mit einem Stentimplantat (10; 50) nach einem der vorhergehenden Ansprüche, und eine separat einsetzbare selbst-expandierende Stentanordnung oder eine separat einsetzbare ballon-expandierbare Stentanordnung.

Revendications

1. Endoprothèse (10 ; 50) comprenant un corps tubulaire (12 ; 52) composé d'un matériau biocompatible comportant une lumière principale le traversant, un bras latéral (20 ; 40 ; 57 ; 60) s'étendant à partir du corps tubulaire, comportant une lumière de bras latéral le traversant et étant fixé au corps tubulaire, le bras latéral comportant une extrémité distale (27) éloignée de son raccord au corps tubulaire, la lumière principale étant en communication fluidique avec la lumière de bras latéral **caractérisée par** une pièce de prolongement tubulaire dépourvue de stent (24 ; 42 ; 59 ; 62) fixée de façon étanche à l'extrémité distale du bras latéral et s'étendant à partir de celle-ci, la pièce de prolongement tubulaire étant repliée dans le bras latéral en vue de la mise en place de l'endoprothèse dans une lumière corporelle et étant extensible à partir du bras latéral lors de la mise en place de l'endoprothèse.

2. Endoprothèse (10 ; 50) selon la revendication 1, dans laquelle la pièce de prolongement tubulaire (24 ; 42 ; 59 ; 62) est repliée à l'intérieur du bras latéral (20 ; 40 ; 57 ; 60) de telle sorte que son extrémité distale (30) soit adjacente à l'extrémité distale (27) du bras latéral.

3. Endoprothèse (50) selon la revendication 1 ou 2, dans laquelle le corps tubulaire est un corps tubulaire bifurqué (52) et dans laquelle le bras latéral est une branche (57) du corps tubulaire bifurqué.

4. Endoprothèse (10 ; 50) selon la revendication 1, 2 ou 3, dans laquelle le corps tubulaire (12 ; 52) et le bras latéral (20 ; 40 ; 57 ; 60) comprennent un matériau tissé ou non tissé biocompatible composé de Dacron ou de PTFE expansé.

5. Endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, dans laquelle la pièce de prolongement (24 ; 42 ; 59 ; 62) comprend un matériau biocompatible élastomère composé de polymère Thoralon™ ou de PTFE expansé.

6. Endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, dans laquelle la pièce de prolongement (42) comprend un renforcement élastique à extension longitudinale (44).

7. Endoprothèse (10 ; 50) selon la revendication 6, dans laquelle le renforcement élastique à extension longitudinale comprend un ruban (44) ou un fil composé de nitinol.

8. Endoprothèse (10 ; 50) selon la revendication 6 ou 7, dans laquelle le renforcement élastique à extension longitudinale (44) est intégré à la pièce de prolongement (42).

9. Endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, dans laquelle la pièce de prolongement (24 ; 42 ; 59) est fixée de façon étanche au bras latéral (20 ; 40 ; 57) par collage à celui-ci.

10. Endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, dans laquelle la pièce de prolongement (24 ; 42 ; 59) comprend le polymère Thoralon™ et la pièce de prolongement est fixée au bras latéral (20 ; 40 ; 57) par collage à celui-ci au moyen d'une solution de Thoralon™.

11. Endoprothèse (10 ; 50) selon l'une quelconque des revendications 1 à 8, dans laquelle la pièce de prolongement (62) est fixée au bras latéral (60) par agrafage à celui-ci.

12. Endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, comprenant un marqueur radio-opaque (28) intégré dans la pièce de prolongement (24 ; 42 ; 59 ; 62).

13. Endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, dans laquelle la pièce de prolongement (42) comprend un renforcement élastique à extension longitudinale (44) intégré à celle-ci, la pièce de prolongement comprend le polymère Thoralon™ ou du PTFE expansé, et dans laquelle au moins un marqueur radio-opaque (28) est intégré dans la pièce de prolongement.

14. Kit comprenant une endoprothèse (10 ; 50) selon l'une quelconque des revendications précédentes, et un ensemble de stent auto-expansible pouvant être mis en place séparément ou un ensemble de stent expansible par ballonnet pouvant être mis en place séparément.

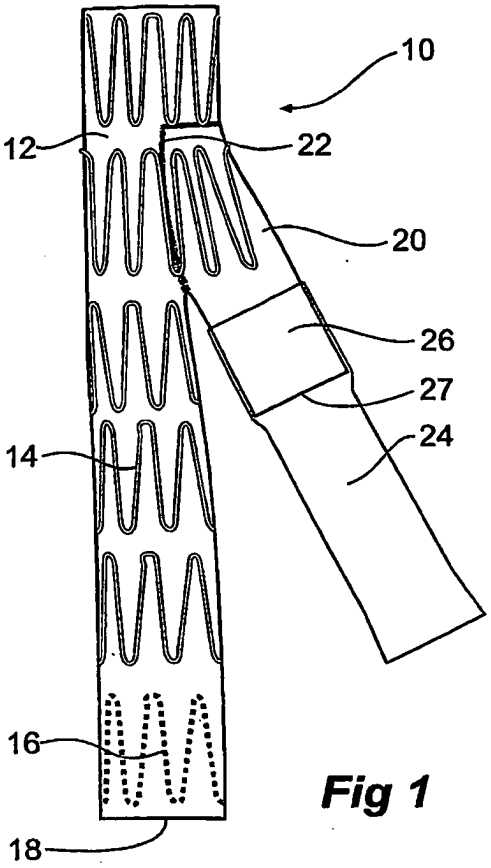

Fig 1

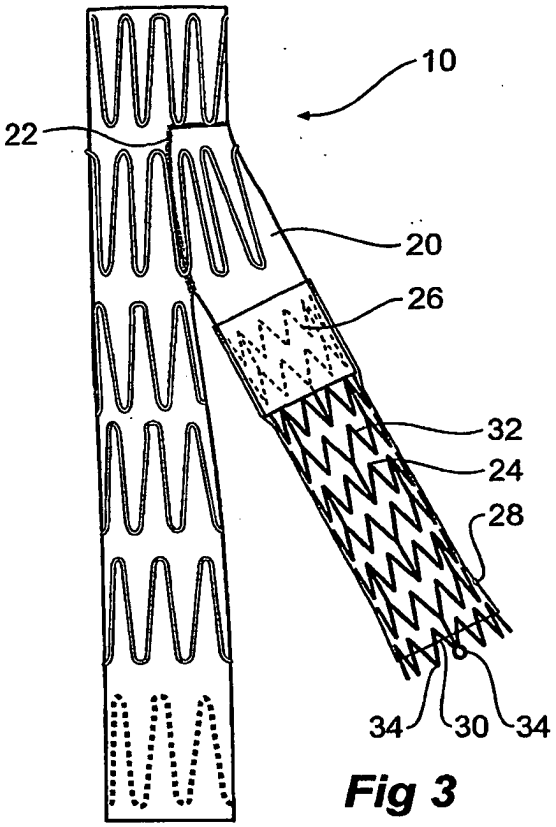

Fig 3

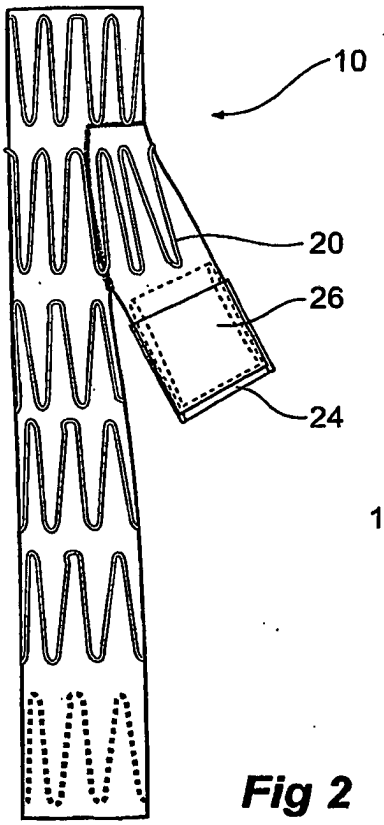

Fig 2

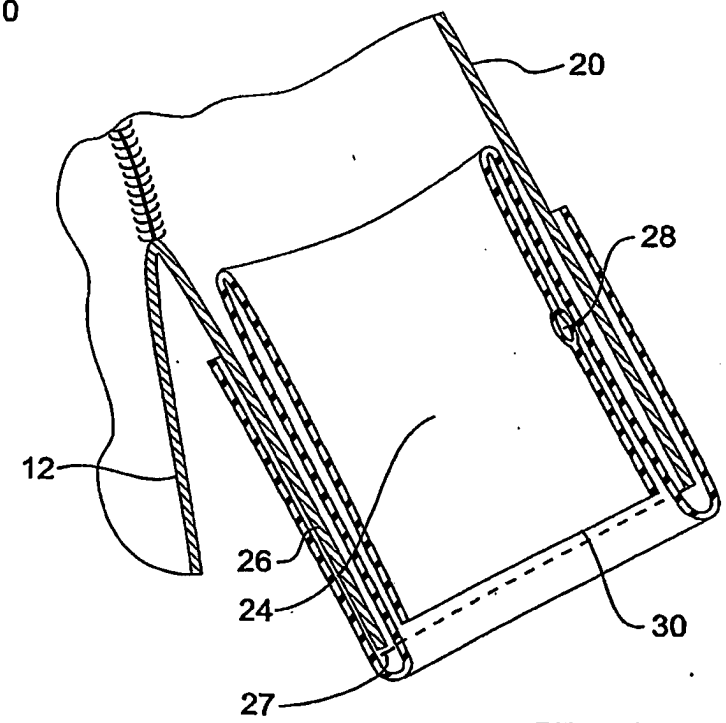

Fig 4

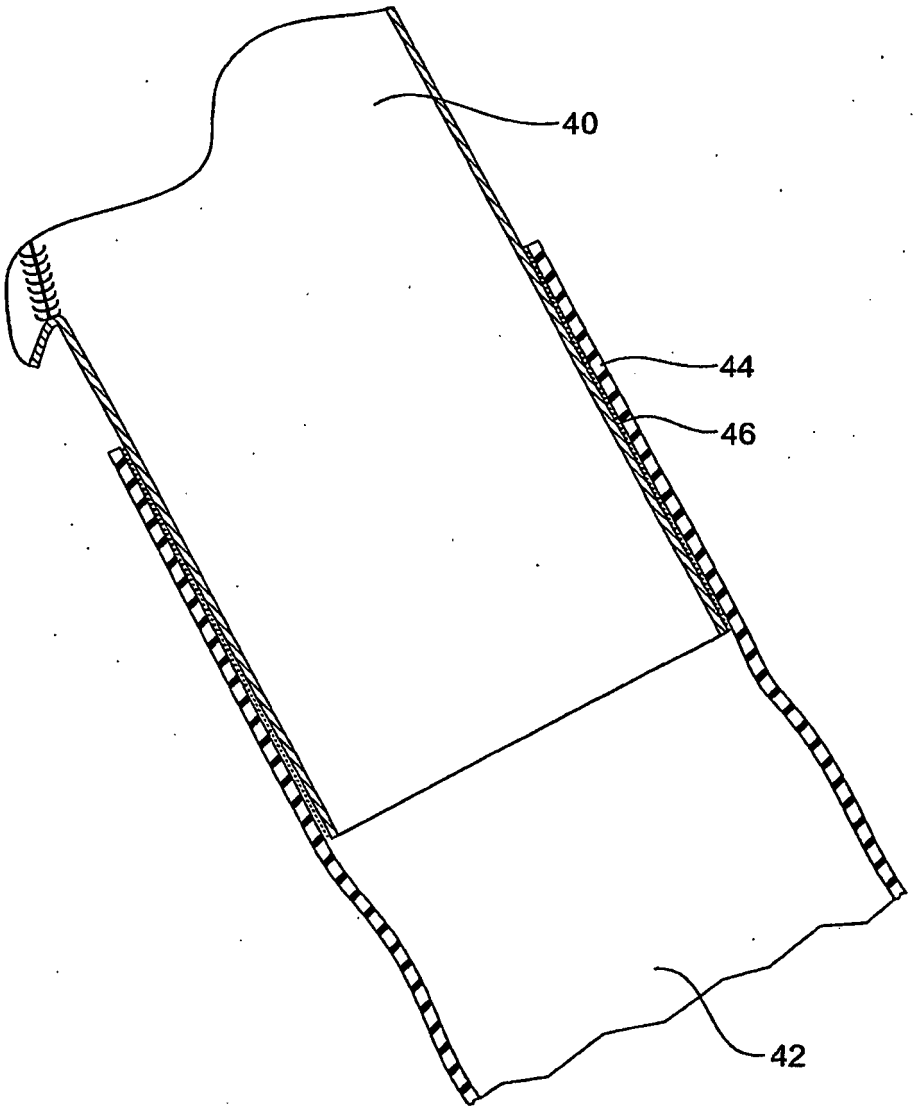

Fig 5

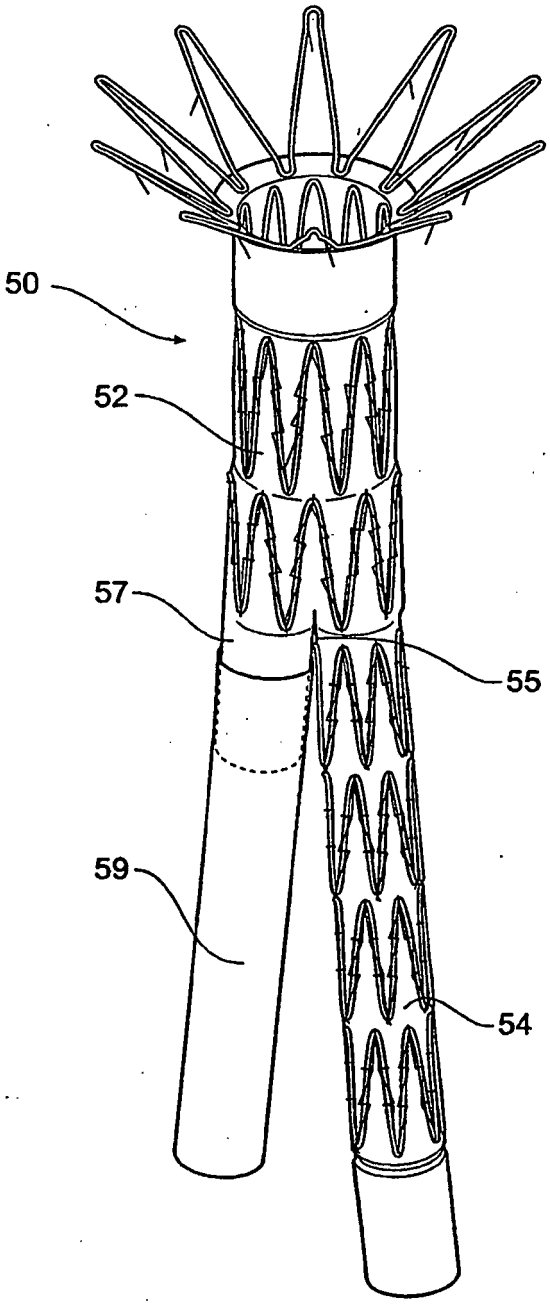

Fig 6

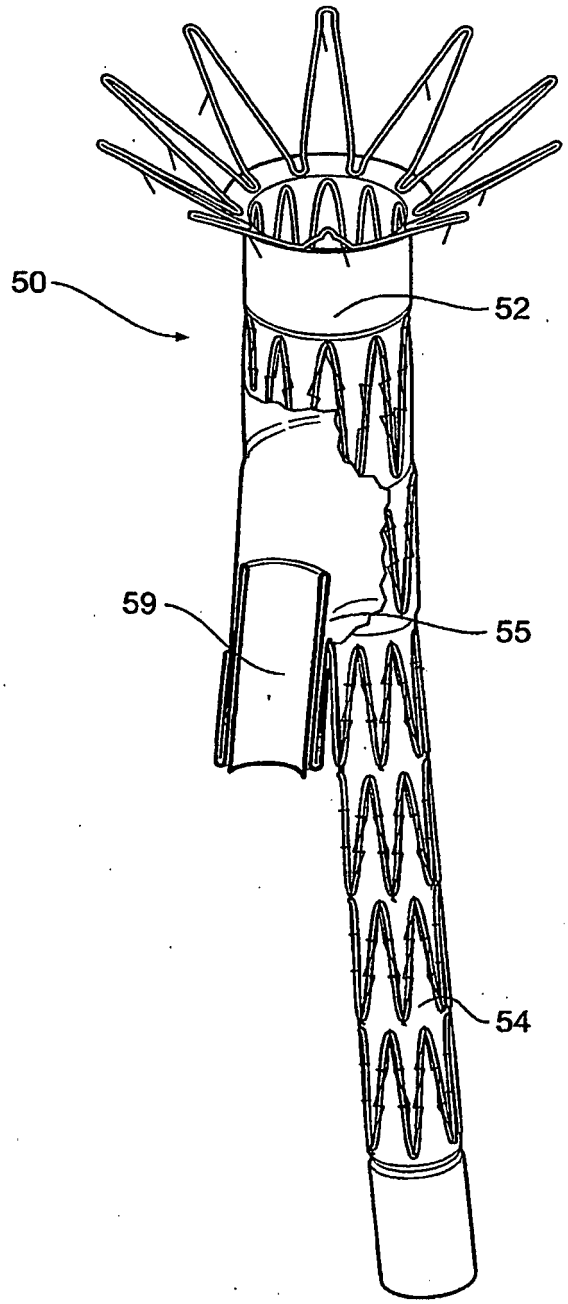

Fig 7

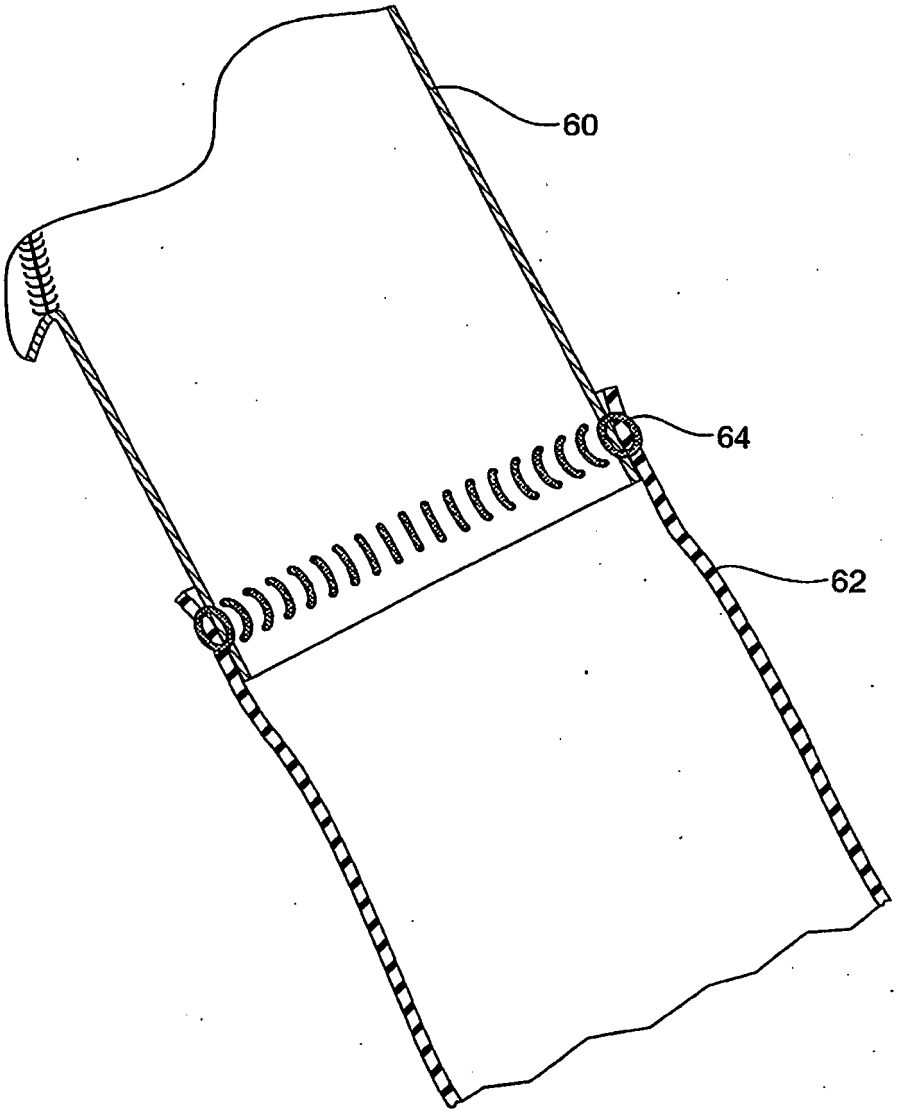

Fig 8

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

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